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10/529,449	03/28/2005	Kazuyuki Yamane	10936-84	8257

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EXAMINER	
TOSCANO, ALICIA	
ART UNIT	PAPER NUMBER
1796	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,449	YAMANE ET AL.	
	Examiner	Art Unit	
	Alicia M. Toscano	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,10,11,18,23,24,26 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,10,11,18,23,24,26 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Objection over Claim 1 is overcome by amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5, 7, 10 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto (JP 2001/323056).

This rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety.

Matsumoto discloses aliphatic polyesters. Said polyesters are the reaction product of polylactic acid and an oxazoline (abstract). The polylactic acid may be produced from the ring opening polymerization of a cyclic dimer [0010]. Polyglycolic acid may be used [0009]. The oxazoline compound may be 2,2'-diphenylene bis(2-oxazoline) [0014], [0021] and examples. The oxazoline is reacted at a temperature of around 220C [0036]. The molecular weight of the polylactic acid, before reaction with oxazoline, is from 50,000 to 300,000 [0010]. When polyglycolic acid is used it is the Examiner's position that one would use the same MW as taught for use for the polylactic acid, since Matsumoto teaches the polymers as functional equivalents. Matsumoto discloses the use of the oxazoline to terminate the carboxyl end groups of

the polylactic acid, however, it is the Examiners position that use of the bis(2-oxazoline) inherently crosslinks, or chain extends, via reaction between two neighboring polylactic acid end groups. Since the oxazoline will inherently bond two ends of neighboring polylactic acid chains the Examiner finds the increase in molecular weight to be inherent in the reaction of Matsumoto. It is the Examiners position that a MW ratio, the property requirements of T2-T1, a PDI of 1.9 and an end MW of 150,000 would be inherent in the composition. Thus, the limitations of Claims 1, 5, 7, 10 and 29-31 are met.

Additionally, since end product requirements are met (see [0010], a MW of 100,000-300,000 is disclosed), the process required to produce said end product is not pertinent unless applicant shows otherwise. Said MW meets the limitations of the claim 1 and its dependants. Since the MW weight and compositional requirements are met the property requirements therein are found inherent.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 5, 7, 10, 29, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5247013).

This rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety.

The high molecular weight aliphatic polyester of claim 1 is viewed as a product-by-process claim and hence the methods they are created by are not pertinent, unless applicant can show a different product is produced.

Shinoda discloses polyesters formed from glycolic acid (Column 1 line 23) having a MW of 155400 and PDI of 3.7 (Table 2 Ex 11, wherein MW=Mn*PDI).

Shinoda does not disclose a product comprising a MW of at least 181,000 as required by the newly amended claims.

Shinoda discloses that the MW is result effective variable. Decreasing the MW increases the rate of hydrolysis and vice versa (Column 3 lines 38-40). Shinoda exemplifies in Table 1, Ex 1-3 that lowering the amount of methyl-glucoside from 20 to 0.018 results in an increase in MW and a decrease in hydrolysis. Ex 11, to which the Examiner referred to above, discloses the use of glycolide with 0.07 wt% methyl-glucoside.

It would have been obvious to one of ordinary skill in the art at the time of the invention to decrease the amount of methyl-glucoside additive during the polymerization of glycolide, as taught by Shinoda, in order to increase the molecular weight and decrease the hydrolysis rate. Given that the PDI of the other examples of glycolide polymerized with an additive are all within the claimed ranges, and that the compositional elements of the claims are met, the Examiner finds the PDI and other properties of the claims to be inherent in the composition of Shinoda.

4. Claims 11, 18, 23, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto.

This rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety.

Matsumoto includes elements of the invention as discussed above. Matsumoto does not disclose a reaction time of between 10 and 30 minutes, as required by Claim 11. The time of reaction will dictate the crosslink density and thus the molecular weight of the polylactic-co-oxazoline product. The molecular weight of the polylactic acid dictates the overall properties of the resin. Higher molecular weight will yield better strength and mechanical properties than low molecular weight polymer however too high of a molecular weight will lead to difficulties with molding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to tailor the reaction time of Masumoto in order to achieve the desired crosslink density, or molecular weight, of the polylactic acid in order to create articles with superior molding properties.

Matsumoto discloses in Ex 6 the use of 2.02 parts by weight oxazoline, or 2.02 wt%, meeting the wt% requirements of the above claims. Since the composition elements and processing conditions are met as previously set forth the properties, chain lengthening, end MW, PDI and (T2-T1) difference therein are found inherent.

5. Claims 1, 5, 7, 10-11, 18 and 23, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore in view of Matsumoto.

This rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety.

Bonsignore discloses the production of high molecular weight polylactic acid or polyglycolic acid. Bonsignore discloses that since relatively small amounts of polylactic acid are used in industry it is very expensive to obtain large MW polylactic acid with high purity and discloses reacting the carboxyl end groups of the polylactic acid with bis-oxazoline (abstract) is a way to obtain the desired purity and MW less expensively (Column 2 lines 14-19). The polylactic acid or polyglycolic acid may be produced by the ring opening polymerization of dilactones (Column 3 Lines 62-65). The molecular weight of the polylactic acid before the reaction is 2,000-15,000 (Column 1 Line 17). The molecular weight after reaction with a bis-oxazoline is 50,000-100,000 (Column 6 Lines 26-28).

Bonsignore does not disclose the use of an end MW of greater than 181K or the use of at least 30,000 MW PGA as a starting material as required by Claims 1 and 11.

Matsumoto includes elements as set forth above. Matsumoto discloses the use of a polylactic acid of MW between 100k and 300k because when the MW is within this range the physical properties, such as strength, are excelled [0010].

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of a MW of 50,000 to 400,000, as taught by Matsumoto, in order to create articles with superior physical properties.

The start range of at least 30,000 and the end range of at least 150,000 lies within this range.

The polydispersity of polymer compositions is high unless specific conditions are met to yield a low PDI. Since the reaction conditions of the polylactic acid has been met the Examiner finds the PDI of at least 1.9 to be inherent in the composition of Bonsignore. As the composition requirements have been met the Examiner finds the properties of Claim 7 to be inherent.

Bonsignore does not include the use of a specific bis-oxazoline nor the amount of bis-oxazoline useful to create high molecular weight polylactic acid.

Matsumoto discloses the use of 0.5-2 wt% 2,2'-m-phenylene bis(2-oxazoline) [0021], Examples, Table 1. 2,2'-m-phenylene bis(2-oxazoline) is preferred because of its stability with the polyester resin [0021], and the amount used is preferred so as to minimize the amount of unreacted bis-oxazline in the composition [0021].

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of 0.5-2 wt% of 2,2'-m-phenylene bis(2-oxazoline), as taught by Matsumoto, since this amount of said species is taught to have superior stability in the resin and this would thusly lead to a superior end product, further meeting the requirements of claims 10, 11, 26 and 28.

Bosignore does not disclose the reaction time. The time of reaction will dictate the crosslink density and thus the molecular weight of the polylactic-co-oxazoline product. The molecular weight of the polylactic acid dictates the overall properties of the resin. Higher molecular weight will yield better strength and mechanical properties than

low molecular weight polymer however too high of a molecular weight will lead to difficulties with molding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to tailor the reaction time of Bonsignore in order to achieve the desired crosslink density, or molecular weight, of the polylactic acid in order to create articles with superior molding properties.

As the compositional requirements are met the Examiner finds the MW increase and further properties such as PDI, T2-T1 difference and weight loss starting temperature required by the Claims to be inherent.

Response to Arguments

6. Applicant's arguments filed 11/3/08 have been fully considered but they are not persuasive. Applicant argues claims 1 and 11 recite specific properties such as the Mw2/Mw1 ratio, the molecular weight distribution, the T2-T1 difference and that a comparison of Exs 1 and 2 show that these properties are not necessarily inherent.

The Examiner disagrees. Examples 1 and 2 merely show that a wt% of less than 1% does not yield the properties of the claims. Matsumoto discloses use of 2 wt% oxazoline. Since the compostion requirements are met (oxazoline and polylactic acid) said properties are deemed inherent. If Applicant wishes to pursue the above rejection the Examiner recommends submitting evidence that when the composition requirements of the claims are met said properties are not inherent.

7. Applicant argues Example 6 only shows the use of lactic acid, not the glycolic acid required by the claims and as such the example does not expressly or inherently describe all the limitations of the claims.

The Examiner disagrees. Matsumoto discloses that either polylactic acid or polyglycolic acid may be used. The reference is not limited to the examples. One would look to the examples to learn how much oxazoline to react with any of the polymers of Matsumoto's disclosure.

8. Applicant argues the MW of the starting polymer of Matsumoto is preferably as high as possible. Applicant argues Matsumoto does not disclose that the end-capping reaction will result in a polymer having 1.65-10.00 times higher molecular weight.

The Examiner disagrees. First, the claims are product by process claims, as long as the product (a high molecular weight polyester reacted with an oxazoline) meets the product requirements (the MW of 181K-500K) the limitations are met. Second, the oxazoline is bi-functional. Thusly, starting with a 100K polymer (which is anticipated by Matsumoto) and reacting with oxazoline will inherently result in some polymer-oxazoline-polymer reactions. Said reaction has a MW which has effectively doubled to 200K, meeting the ratio requirements of the claim.

9. Applicant argues Matsumoto recognizes the end-capped product has no appreciable increase in molecular weight.

The Examiner disagrees. No evidence or support for this argument is found in Matsumoto. It is unclear why, when the composition and reaction conditions are met, said increase would not be inherent. Applicant has offered no evidence to the contrary.

10. Applicant argues the only showing in Matsumoto of use of a glycolide polymer is Example 3 and as such the Examiner must only rely on such in the rejection.

The Examiner disagrees. The reference is not limited to the examples. The disclosure anticipates either polylactic acid or polyglycolic acid. It is unclear to the Examiner why one reading the reference would believe that the oxazoline wt% taught in Ex 3 was the only suitable wt% for polyglycolic acid when Matsumoto discloses that the polymers may be used interchangeably. The Examiner requests evidence of unexpected results stemming form the use of polyglycolic acid.

11. Applicant argues they only have the burden of showing the product is not inherent in Matsumoto if the Examiner shows that Matsumoto discloses the same process.

The Examiner disagrees. In a product by process claim the process is not given patentable weight unless Applicant shows a different product is produced. Applicant has not shown such.

12. Applicant argues the Examiner's assertion that the reaction of Matsumoto is carried to completion and as such the same reaction is unsupported by the evidence of record in that Matsumoto teaches extra oxazoline may be in the product.

The Examiner disagrees. Matsumoto discloses that one may choose to have excess oxazoline in the composition (i.e. more oxazoline that is needed to convert all the carboxyl groups), and doing such gives superior heat resistance and stability [0021]. As such Applicants arguments that this is evidence of the reaction not being carried to completion are not found persuasive.

13. Regarding Shinoda Applicant argues the Examiner has ignored signification limitations of claim 1 and obviousness and inherency are different concept. Applicant argues the Examples of Shinoda are drawn to lactide polymers, not glycolide polymers. As such Applicant argues the conclusions made therein are improper.

The Examiner disagrees. The reference is not limited to the examples. Though Shinoda exemplifies lactide polymers, glycolide may be used (as previously set forth). It is unclear why, when both polymers are anticipated and when both polymers are very similar molecularly, that similar results would not be seen when using glycolide in the examples of Shinoda. As such Applicant's arguments to such are not persuasive. Since the composition requirements has been made (though through a case of obviousness), it is unclear to the Examiner why the claimed properties would not be inherent. The Examiner requests evidence to the contrary.

14. Regarding Bonsignore Applicant argues Bonsignore discloses lower MW polymers than those claimed and that Bonsignore does not teach the functional equivalence of lactic and glycolic acid. Applicant argues combination with Matsumoto is improper since Matsumoto is only drawn to end-capping reactions.

The Examiner disagrees. Bonsignore discloses that it is cost effective to produce higher MW polylactic or polyglycolic acid polymers by using oxazoline as a coupling agent. This is the same reason applicant is doing such. Though Matsumoto is drawn to endcapping, one looking for reaction conditions or similar types of reactions would look to Matsumoto since Matsumoto is drawn to the same reaction. In light of Matsumoto one would recognized that you could start with higher MW polymers in order to end with

higher MW polymers. The motivation to combine, i.e. because higher MW polymers have superior properties, is proper. Regarding the functional equivalence, it is unclear to the Examiner why, when both polymers are taught to be used interchangeably in the reaction, this is not a showing of functional equivalence. Evidence or unexpected results regarding such is requested.

Conclusion

All claims are drawn to the same invention claimed previously and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered earlier. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after a request for continued examination under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT

/Randy Gulakowski/

Supervisory Patent Examiner, Art Unit 1796